

14. (Cancelled)

REMARKS: CLAIM REJECTION UNDER 35 U.S.C. § 103(a)

Claims 1-10, 12, and 13 stand rejected under 35 U.S.C. §103(a) ("Section 103(a)") as obvious over U.S. Patent No. 6,436,449 (issued Aug. 20, 2002) ("Gidlund"). Applicant respectfully submits that Gidlund fails to teach the claim limitations recited in the present application because 1) Gidlund does not teach administering low dosages that produce selective Cox-2 inhibition; and 2) Gidlund teaches methods for treating tinnitus not methods for treating pain through selective COX-2 inhibition. M.P.E.P. § 2142.

1. Gidlund Teaches the Use of Extracts Not Juice

The independent claims of the present invention include a limitation on the total amount of juice administered daily. Because Gidlund teaches that, "The liquid extract from the *Morinda Citrifolia* will be present in the medicament in the amount such as to provide a daily dosage of 0.1-2 ml, or 0.2-1 ml, e.g., 0.4-0.7 ml, per kg body weight of the patient," Gidlund fails to teach every claimed limitation of the present invention. ~~Gidlund generally teaches the use of an extract derived from the bulk or the roots of Morinda Citrifolia for the manufacture of a medicament and treatment of a mammal suffering from tinnitus and provides specific instructions and in column 5, lines 16-19 that any liquid extract would be administered through patient at a minimum dosage of .1 ml per kg of body weight of a patient. Accordingly, a 70 kg patient would be administered 7 ml of liquid extract from Morinda Citrifolia each day.~~

~~The detail~~ As described in example 1 of the specification of the present application, the dosaging of *Morinda Citrifolia* juice is critical to achieving selective Cox-2 inhibition.

If an excessive amount of juice is administered, the selective Cox-2 properties of the *Morinda Citrifolia* juice are diminished. Because Gidlund teaches the administration of a quantity of juice that is higher than the amount necessary to achieve said selective Cox-2 inhibition, the disclosure in Gidlund fails to read on the claims of the present invention.

2. Gidlund Does Not Teach a Method for Reducing Pain By Selective COX-2 Inhibition

The difference between treatment of pain and selective COX-2 inhibition is patentable. COX-2 expression is associated with pain and inflammation. COX-1 is a constitutively active enzyme responsible, among other things, for maintaining the mucosal lining of the stomach. When COX-2 is inhibited, pain is reduced. When COX-1 is inhibited, patients experience uncomfortable side effects including gastric ulcers.

Compounds or formulations, which favorably influence pain, do not have a reasonable probability for reducing pain by selective COX-2 inhibition. For example, a popular treatment of chronic pain and inflammation involves the use of non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs inhibit both COX-2 and COX-1. While NSAIDs have been effective in reducing inflammation and pain, NSAIDs have a number of adverse side effects. The major side effects of NSAIDs are gastrointestinal related. In order to provide relief from pain associated with COX-2 without inhibiting COX-1, drug companies have attempted to produce selective COX-2 inhibitors (e.g. VIOXX).

Applicant's claims create limitations which require that the juice be administered in small dosages in order to limit undesired COX-1 inhibition... Applicants' disclosure demonstrates the importance and non-obviousness of administering the appropriate concentration of *Morinda citrifolia*. Applicants' experiments provide the non-obvious discovery that at some

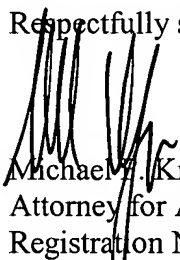
concentrations, selective COX-2 inhibition was achieved, and at other concentrations it was not. Specification, pg. 15. The Applicants indicated, "The data suggests the surprising result that in some circumstances 'less' *Morinda citrifolia* juice provides 'more' inhibition selectivity." Specification, pg. 15. Applicants' disclosure shows that COX-2 selectivity is undermined by excessive, increased concentrations. Specification, pg. 15. It is only after the inherent COX-1 inhibiting qualities of *Morinda citrifolia* are limited by the methods of the present invention that selective COX-2 inhibition occurs.

CONCLUSION

Because the cited prior art fails to teach or suggest all claim limitations of the present invention, Applicants submit that the present invention is not obvious. Applicants submit that the claims are now in condition for allowance. Accordingly, Applicants request favorable reconsideration. If the Examiner has any questions or concerns regarding this communication, the Examiner is invited to call the undersigned.

DATED this 22 day of Nov., 2005.

Respectfully submitted,


Michael M. Krieger
Attorney for Applicant
Registration No. 35,232

KIRTON & McCONKIE
1800 Eagle Gate Tower
60 East South Temple
Salt Lake City, Utah 84111
Telephone: (801) 321-4814
Facsimile: (801) 321-4893

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